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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC., Plaintiff, v. SPD SWISS PRECISION DIAGNOSTICS GMBH, Defendant.	Case No. 14-CV-585 (AJN) **SPD SWISS PRECISION DIAGNOSTICS GMBH'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS** The Hon. Alison J. Nathan Trial Date: None Set

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INTRODUCTION

The complaint of plaintiff Church & Dwight Co., Inc. ("C&D") should be dismissed for failure to state a claim. The product at issue here – Clearblue Advanced Pregnancy Test with Weeks Estimator (the "Weeks Estimator" or the "Product") – is a device regulated by the U.S. Food & Drug Administration ("FDA"). The Product is a home pregnancy test that, in addition to informing a woman whether she is pregnant, also estimates (in the case of a positive result) a range of weeks since she last ovulated. That is, it estimates when she conceived and therefore when pregnancy began.

During FDA's clearance process for the Weeks Estimator, FDA reviewed the Product's packaging and approved it, subject to certain limitations and disclosures aimed at avoiding confusion over differences in methods for estimating when pregnancy begins. After the Product was launched in August 2013, the FDA contacted SPD Swiss Precision Diagnostics GmbH ("SPD") with issues about whether SPD was complying with the FDA's requirements, and thereafter engaged in a second review of the Product's packaging and other advertising materials. After that review, the FDA approved revised packaging for the Weeks Estimator, as well as a mitigation plan for the various issues raised by the FDA.

C&D's complaint is based on the allegation that the Weeks Estimator is not capable of estimating how many weeks a woman has been pregnant because, according to C&D, the FDA "specifically directed that the Product not be marketed for that use." Indeed, C&D maintains that the date of a woman's last menstrual period, and not the date of ovulation, is the only medically accepted reference point for determining when pregnancy begins. (Compl. ¶ 18.) C&D challenges various advertising materials on this theory.

Assuming these false allegations were true, as one is required to do on a motion to dismiss under Rule 12(b)(6), C&D's claims are nonetheless barred because they constitute an

impermissible attempt to circumvent the FDA's decision to approve the marketing of the Weeks Estimator product – including approval of labeling essentially identical to what C&D is challenging here. Indeed, pursuant to its statutory authority under the federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA ***already considered*** the precise "risks" exaggerated in C&D's complaint before the FDA cleared the Weeks Estimator to be marketed in the U.S. in accordance with the claims and disclosures on the product's labeling. All of the challenged advertising comports substantively with statements approved as accurate by the FDA.

Courts, including this one, have repeatedly held that private parties are not permitted to undermine the FDA's considered judgments through private litigation under the Lanham Act. Here, the questions implicated by C&D's complaint – whether ovulation marks the beginning of pregnancy; whether the FDA-mandated disclosures are effective to avoid misunderstandings by its users; whether any potential health risks due to "off-label" use of the Product are outweighed by the Weeks Estimator's benefits to consumers; and whether SPD has marketed the Weeks Estimator consistently with the FDA-imposed restrictions – are not appropriate for private adjudication under the Lanham Act. Rather, they are regulatory enforcement and technical expertise issues falling squarely within the exclusive purview of the FDA to regulate home pregnancy test products.

According to C&D's own allegations, adjudicating whether SPD's marketing of the Weeks Estimator violates the Lanham Act necessarily requires a determination that SPD's labeling and marketing of the Weeks Estimator contravenes the limitations imposed by the FDA. Indeed, C&D's complaint asks this Court to reverse the FDA's determination that the statements and labeling it ***approved*** for the Weeks Estimator are nonetheless insufficient to protect users from confusion and harm. The appropriate forum for C&D's complaint, if anywhere, is before the FDA, not a court. If the FDA shares C&D's wildly inflated concerns, or wishes to reconsider

its approval of the Weeks Estimator labeling, it can act. But C&D's complaint should be dismissed.

BACKGROUND

C&D and SPD are competitors in the market for home pregnancy test kits. (Compl. ¶ 2.) C&D markets products under the First Response brand, among others. SPD markets its products under the Clearblue brand, among others. (Compl. ¶ 15.) In August 2013, SPD launched the Clearblue Advanced Digital Pregnancy Test With Weeks Estimator" (the "Weeks Estimator" or the "Product") in the U.S. (Compl. ¶ 2.) Like other home pregnancy tests, SPD's Weeks Estimator is designed to tell a woman whether she is pregnant. But unlike all other home pregnancy tests, the Weeks Estimator also tells a woman, if she obtains a pregnant result, how many weeks may have passed since she ovulated (in 3 result categories: 1-2, 2-3 and 3+ weeks) by measuring levels of human chorionic gonadotropin ("hCG"), a pregnancy-related hormone. (*See* Compl. ¶¶ 3, 17.)

A. The Weeks Estimator Product Is A Medical Device Regulated By The U.S. Food and Drug Administration.

The FDCA, as amended by the Medical Devices Amendments of 1976, separates medical devices into three categories for purposes of the level of regulatory scrutiny they receive. "Class I" devices present "no unreasonable risk of illness or injury" and therefore are subject to minimal regulation. "Class II" devices present greater potential risk of harm and are therefore subject to somewhat greater regulatory scrutiny. "Class III" devices either "present a potential unreasonable risk of illness or injury" or are "purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." Class III devices are subject to the strictest regulatory scrutiny. *See generally*, 21 U.S.C. § 360c(a), *et seq*.

Home pregnancy tests, such as the Weeks Estimator, are considered Class II medical devices. (Compl. ¶ 20.) The FDA does not permit a new home pregnancy test to be marketed unless the manufacturer has received clearance by the agency for the product to be marketed for a particular "intended use." (*Id.*) The review process for a new home pregnancy test product is commenced by the filing of a premarket notification submission to the FDA (known as a 510(k) submission). 21 C.F.R. § 807.81. The 510(k) submission provides a description of the new device, and a description of the intended use of the product, including "a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended." 21 C.F.R. § 807.92. (Compl. ¶ 20.)

The 510(k) application is intended to demonstrate to the FDA that the device is at least as safe and effective as – i.e., "substantially equivalent" or "SE" to – a legally marketed predicate device. 21 C.F.R. § 807.92. Hence, before marketing a Class II device, the submitter must receive a letter from the FDA that finds the device to be substantially equivalent, and states that the device can now be marketed in the US. This "clears" the device for commercial distribution, and so is generally referred to as a "clearance letter" or "SE letter." (Request for Judicial Notice In Support of Motion to Dismiss ("RJN"), ¶ 1, Exh. A.) On December 10, 2012, SPD received a clearance letter following submission of a 510(k) for the Weeks Estimator. (Compl., Exh. A [the FDA's December 10, 2012 Clearance Letter] (the "Clearance Letter").)

B. The FDA Applied Enhanced Scrutiny Over The Approval And Labeling For The Weeks Estimator Due To Its Finding Of A Heightened Risk Of Off-Label Use By Consumers.

In the course of the FDA's review of the Product, the FDA's Office of In Vitro Diagnostics and Radiological Health ("OIVD") identified a concern over the proposed labeling of the Product: that women would misinterpret the product's results. (*See* Clearance Letter, p. 1.;

Compl. ¶ 22.) The FDA's articulated concerns paralleled some of those asserted in C&D's Complaint. (*Id.*) The FDA noted that the Weeks Estimator result "is not aligned with gestational aging done by healthcare professionals (i.e., it will under-estimate gestational age by an average of 2 weeks)." (RJN, ¶ 2, Exh. B [Sept. 12 FDA Hold Letter] (the "Hold Letter").) In particular, the FDA's concern was that users may:

> misinterpret weeks results to be a substitution for gestational age determination or may misinterpret weeks results to mean they are pregnant and their pregnancy is progressing in a healthy manner (e.g., because they are moving from 1-2 weeks to 2-3 weeks to 3+ weeks according to device results). These misinterpretations may cause the user to delay or forego necessary care by a healthcare professional. For example, uses may not recognize symptoms of ectopic pregnancy because of improper assumptions based on this device output and may not seek appropriate medical care.

(*Id.*)

The FDA was clear about how its concerns over user misinterpretation of the Weeks Estimator results should be resolved: after noting that the existing Indications for Use ("IFU") described in SPD's 510(k) submission and labeling were inadequate to guard against such misinterpretations, it concluded that "[d]elay in appropriate care in these situations is a harmful health impact ***that may be prevented given adequate device labeling.***" (*Id.* (emphasis added).)

The FDA then invoked Section 513(i)(1)(E) of the FDCA, a specific statutory procedure under which the FDA evaluates a new Class II medical device with heightened scrutiny. If it then clears the subject device to be marketed, its clearance letter is referred to as a "SE With Limitations" (i.e., "substantial equivalence" *with limitations*) instead of the usual "SE" clearance letter. In particular, Section 513(i)(1)(E) gives the FDA Director who is responsible for the division governing the product at issue – in this case the FDA's Office of In Vitro Diagnostics

and Radiological Health (OIVD) – additional power to control the actual labeling and other advertising for the product.[1] 21 U.S.C. §360c(i)(1)(E). Section 513(i) provides that "when determining that a device can be found substantially equivalent to a legally marketed device" – *i.e.*, cleared for sale – "the . . . Director . . . may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if . . . the Director determines and states in writing – (I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device," *i.e.*, an off-label use, and "(II) that such use could cause harm." *Id.* Section 513(i) then instructs the Director to, *inter alia*, "*specify the limitations* on the use of the device. . ." and "find the device substantially equivalent" if it meets the general requirements for SE clearance *and* "conforms with the specified limitations." *Id.* (emphasis added). The Director is not permitted to delegate this responsibility. *Id.* An SE With Limitations, therefore, *obligates* the FDA's Director to specify limitations, most often in the form of language on product labeling and in advertising, that will prevent consumers from using the device in an off-label way that could cause harm. (*See* RJN, ¶ 3, Exh. C.)

In invoking Section 513(i)(1)(E) of the FDCA, the FDA issued what is known as a hold letter. (*See* RJN, ¶ 2, Exh. B.) The Hold Letter in this case notified SPD that the FDA would place the 510(k) submission for the Weeks Estimator on hold pending receipt of certain additional information, and directed SPD to submit updated proposed labeling containing a revised IFU statement. (*Id.*)

[1]The term "labeling" under the FDCA means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

C. The FDA Approves The Labeling And Marketing Of the Weeks Estimator Product.

After FDA invoked its special authority under Section 513(i), FDA and SPD engaged in a detailed dialogue about the limitations and disclosures to be required for the Weeks Estimator package and product insert. (*See* RJN, ¶¶ 4-6, Exhs. D, E, F.) Then, on November 27, 2012, FDA sent an email to SPD indicating that the labeling SPD had provided to FDA in response to the Hold Letter "appears to meet our requests." (RJN, ¶ 7, Exh. G.) On December 10, 2012, the FDA issued its Clearance Letter, an SE With Limitations, clearing SPD to begin marketing the Weeks Estimator. The Clearance Letter specified essentially the same limitations on the Product's box and the package insert (as well as other marketing materials) as those that had been communicated in the Hold Letter and subsequent correspondence. (Clearance Letter, pp. 1, 3; Compl. ¶ 17.)

D. The FDA's 2013-2014 Instructions To Modify Advertising.

On November 12, 2013, SPD received an email from FDA, stating that "[i]t has come to our attention that SPD is marketing the 'Clearblue Advanced Pregnancy Test with Weeks Estimator' device in violation of the limitations in the FDA's clearance letter." (RJN, ¶ 8, Exh. H.) The email did not state how this issue came to FDA's attention, but FDA requested a teleconference "to communicate our concerns and receive further clarifications." (*Id.*)

The concerns the FDA outlined in the teleconference paralleled certain aspects of the challenges C&D advances in its complaint. (*Id.*) With respect to the Product carton, the FDA expressed concern about the insertion of the word "weeks" in the depicted display window and required that it be removed and replaced with the words "weeks along" outside the window – acknowledging and repeating that it had approved the latter phrase in the clearance process. (*Id.*) Notably, the stated basis of the FDA's concern about the use of the word "weeks" inside the

display window was that the Product window itself does not literally display the word "weeks" when it returns a positive result, and so the windows on the package did not accurately reflect the actual windows on the test sticks. (*Id.*)

On November 22, 2013, SPD submitted an overall mitigation plan and drafts of packaging that removed the word "weeks" from the display windows and replaced it with the words "weeks along" beneath the display windows as originally approved by the FDA. Except to request a revision to the font size of the phrase "weeks along," and to request an asterisk directing consumers to the IFU on the side of the pack, the FDA approved the packaging. (RJN, ¶ 9, Exh. I.)

E. C&D's False Advertising Action

On January 29, 2014, C&D filed this Action, alleging that SPD's marketing of the Weeks Estimator constitutes false advertising under the Lanham Act and Section 349 of the New York General Business Law. (Compl. ¶¶ 63-70, 71-75.) The complaint also includes a cause of action [redacted]

The gravamen of C&D's false advertising claims is the allegation that the labeling of the Weeks Estimator (and certain other advertising) falsely communicates that the Product estimates how long a woman has been pregnant in violation of purported FDA constraints. According to C&D, only the date of a woman's last menstrual period – not the date of ovulation – is a medically accepted reference point for estimating when pregnancy begins.

Even assuming the truth of these allegations (they are, however, false), C&D has failed to state actionable claims under the Lanham Act or New York law because a determination of its claims invades the exclusive domain of the FDA to regulate home pregnancy tests under FDCA. Accordingly, C&D's false advertising claims should be dismissed.

ARGUMENT

I. The Legal Standard For A Motion To Dismiss Under Rule 12(b)(6)

Rule 12(b)(6) allows dismissal of a claim when the pleadings fail to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). In order to survive dismissal, a plaintiff must assert a cognizable cause of action and allege facts that, if true, would support the claim. *Subaru Distributors Corp. v. Subaru of America, Inc.*, 425 F.3d 119, 122 (2d Cir. 2005). Dismissal is warranted where the complaint states no "actionable" grounds for relief. *Roche v. Adkins*, 998 F.2d 1016 (7th Cir. 1993).

In determining the adequacy of the complaint, a court may consider "any written instrument attached to the complaint as an exhibit or incorporated in the complaint by reference, documents upon which the complaint relies and which are integral to the complaint," *Subaru Distributors Corp. v. Subaru of America, Inc.*, 425 F.3d 119, 122 (2d Cir. 2005), as well as matters of which judicial notice may be taken. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Even if a document is not incorporated by reference, the court may nevertheless consider it, without converting a Rule 12(b)(6) motion into one for summary judgment, where the "complaint relies heavily upon its terms and effect." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (quotations omitted).[2]

II. C&D's Lanham Act Claims Are Precluded Because They Seek To Enforce The FDCA And Undermine FDA Decisions.

The FDCA comprehensively regulates medical devices. 21 U.S.C § 301 *et seq.* The FDA is charged with investigating potential violations, *id.* §372, and has a number of

[2] SPD submits that, without referencing any facts beyond the complaint and clearance letter, the Court can and should determine that this action is barred under authorities cited below. That is, while SPD believes that the other documents are judicially noticeable, they are not *necessary* to reach the conclusion that the case must be dismissed. *See* SPD's accompanying RJN filed concurrently herewith.

enforcement powers. These range from injunction proceedings, to civil monetary penalties, product seizure, and recalls. *See* 21 U.S.C §§332-334; 21 C.F.R. § 810.10 *et seq.* (*e.g.*, the FDA has authority to order recalls of medical devices if it "finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death."). In addition, citizens may petition the FDA to take action. 21 C.F.R. §§10.25(a), 10.30. Under section 337 of the FDCA, however, enforcement power resides *exclusively* with the FDA and the U.S. Department of Justice. There is no private right of action to enforce the FDCA. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990).

Against this statutory background, courts have consistently rejected attempts to circumvent the prohibition on private enforcement – or to undermine the FDA's exclusive authority – by the assertion of a Lanham Act challenge that would have such an effect. *See, e.g, Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 96-2459-JWL, 1997 WL 94237 (D. Kan. Feb. 26, 1997) ("[B]ecause no private right of action exists under the FDCA, a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation."). The judiciary has been especially reluctant to tread in the FDA-dominated areas of product labeling and medical devices. For example, in *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1177 (9th Cir. 2012) *cert. granted*, 134 S. Ct. 895 (2014), the Ninth Circuit affirmed summary judgment barring a Lanham Act challenge to the labeling on a juice product. After noting that this is an area subject to extensive regulation by the FDA, the Court explained its ruling:

> Despite speaking extensively to how prominently required words or statements must appear, the FDA has not (so far as we can tell) required [what the challenger claims is necessary to avoid deception]. . . If the FDA believes that more should be done to prevent deception, or that [the advertiser's label] misleads consumers, it can act. But under our precedent, for a court to act when the FDA has not – despite regulating extensively in the area – would risk undercutting the FDA's expert judgments and authority.

Id. at 1117.

The *Pom Wonderful* decision relied heavily on the Ninth Circuit's earlier decision in *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), which is especially apt here. There, a Class II medical device manufacturer, PhotoMedex, brought a Lanham Act claim against a competitor, Ra Medical Systems, alleging that Ra was misleading consumers about whether Ra's product had received a 510(k) clearance from the FDA. While Ra had received a clearance for an earlier version of the pertinent product, PhotoMedex contended that the new version of the product had been modified to a degree that a new clearance was necessary.

PhotoMedex contacted the FDA repeatedly, demanding "immediate enforcement action against Ra Medical." The FDA responded only that it would "evaluate" the matter to determine whether enforcement action was appropriate." *Id.* at 926. But the agency "never reached the conclusion sought by PhotoMedex."

The Ninth Circuit affirmed summary judgment in favor of Ra. In a passage of particular application here, the court explained:

> The statute assigns to the FDA the responsibility for taking enforcement action against Defendants. The FDA action could have taken different forms, including a clear statement that the Pharos was not covered by the prior clearance of the SurgiLight laser, an effort to stop Defendants from marketing their Pharos device, or action to impose a civil monetary penalty. The FDA did none of those things, however.

Id. at 928; *see also, Pom,* 679 F.3d 1170 ("PhotoMedex teaches that courts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments"); *PDK Labs, Inc. v Friedlander,* 103 F.3d 1105 (2d Cir. 1997) (claim barred because it seeks to privately enforce the FDCA); *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-32 (3d Cir. 1990) (denying request for preliminary injunction; Lanham Act challenge to cough syrup label as misleading was barred because issue of whether an ingredient

is "inactive" was the subject of an FDA regulation and it is inappropriate for a federal court to use the Lanham Act "to determine preemptively how a federal administrative agency will interpret and enforce its own regulations"); *Rita Medical Systems, Inc. v. Resect Medical, Inc.,* 2006 U.S. Dist LEXIS 52366 (N.D. Cal. 2006) (preliminary injunction denied because Lanham Act claim would require court to evaluate whether the challenged claims are consistent with the 510(k) clearance for the medical device); *Braintree Laboratories,* 1997 U.S. Dist. LEXIS 2372 (motion to dismiss for failure to state a claim granted because Lanham Act claims "that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA"); *Summit Tech., Inc. v. High-Line Med. Instruments Co.,* 933 F. Supp. 918 (C.D. Cal 1996) (motion to dismiss Lanham Act claim regarding medical device granted because "the FDA has not yet determined how it will interpret and enforce its own regulations with regard to this question, and the Court must therefore decline to usurp the FDA's authority").

This Court, too, has repeatedly declined to allow a Lanham Act claim to proceed when it would risk substituting the Court's discretion for that of the FDA. In *Cytyc Corp. v. Neuromedical Systems, Inc.,* 12 F. Supp. 2d 296, 302 (S.D.N.Y. 1998), this Court dismissed a Lanham Act claim under Rule 12(b)(6) because advertising representations "that comport substantively with statements approved as accurate by the FDA cannot supply the basis" for such a claim. *See also SmithKline Beecham v Johnson & Johnson,* 1996 U.S. Dist. LEXIS 7257 (S.D.N.Y 1996) (preliminary injunction denied because challenged advertising was based on labeling approved by the FDA).

In *American Home Products Corp. v. Johnson & Johnson,* 672 F. Supp. 135, 145 (S.D.N.Y 1987), McNeilab, maker of Tylenol, claimed that American Home Products, maker of Anacin and Advil, engaged in false advertising under the Lanham Act. The FDA had mandated

that the packaging for Anacin contain a warning concerning the serious and even fatal risks of Reye Syndrome from giving Anacin to children and teenagers to treat symptoms of influenza and chicken pox. *Id.* The labeling on packaging for Anacin, however, contained the word "SAFE" in prominent letters on the front of the package with the FDA-required warning regarding the risks of Reye Syndrome relegated to the "fine print" on the back. Granting American Home Products' motion for summary judgment, the court explained:

> It is true that the [Reye Syndrome] warning is buried in the fine print on the back of the Anacin package, while the front bears in large block letters the legend "SAFE, FAST PAIN RELIEF." This obviously creates the possibility that Anacin could be administered to a child or teenager with flu or chicken pox by a parent who perceived only a message of safety without being alerted to the danger, or taken by such a youngster on his or her own initiative without any suspicion of hazard. ***The consequences of such a mistake may be serious or even fatal. But this is a problem to be addressed by the FDA and not by the courts in a Lanham Act suit***. Indeed, it is a problem which the FDA has already addressed, when it specifically approved the Anacin label in its entirety. There is no apparent reason why McNeil cannot ask the FDA to reconsider that approval in light of the survey evidence it has presented here to show the message users take from the Anacin package.

American Home, 672 F. Supp. at 145 (all emphasis added).[3]

According to *American Home Products*, a competitor is precluded from challenging the sufficiency of a product's label and marketing claims when the FDA has already approved those claims fully cognizant the risk of potential harm (including death) resulting from consumer misunderstanding about the IFU and performance of the product.

As in *American Home Products*, as well as *PhotoMedex*, and *Pom Wonderful*, C&D's

[3] C&D may argue that some these cases are inapposite because they involve pharmaceuticals, over which FDA *usually* has more power to regulate specific advertising language than over medical devices. But in this case, FDA was issuing an SE with limitations, which, pursuant to 21 U.S.C. §360c(i)(1)(E), gives FDA not just the right but the *obligation* to dictate advertising language protective of consumers. These cases are therefore directly on point.

allegations fall squarely within the prohibition against circumventing the rule against private enforcement of the FDCA. C&D's complaint is littered with admissions that the Weeks Estimator is regulated by the FDA, and indeed relies on the contention that SPD's has failed to comply with the FDA's mandates:

- "SPD has falsely advertised the Product as being capable of estimating how many weeks a woman has been pregnant, notwithstanding . . . that the ***[FDA], which regulates home pregnancy tests, specifically directed*** that the Product not be marketed for that use." (Compl. ¶ 2.)[4]
- "The ***FDA cleared*** the Product to be marketed for the former use, but ***expressly prohibited SPD*** from marketing the Product as a means for estimating the length of pregnancy." (Compl. ¶ 3.)
- "The FDA explicitly warned SPD . . . and in unmistakable and forceful language, ***prohibited SPD*** from marketing the Product . . ." (*Id.*)
- "By opting to begin marketing the Product pursuant to the FDA's clearance letter, SPD accepted the ***restrictions and limitations*** contained therein." (Compl. ¶ 4.)
- "The FDA determined that it ***cannot be marketed*** for that purpose. . ." (Compl. ¶ 5.)
- "[H]ome pregnancy test kits are considered to be medical devices and are ***regulated by the FDA***. The ***FDA does not permit*** a new home pregnancy test kit to be marketed unless the manufacturer has received clearance by the agency for the product to be marketed for a particular 'intended use.'" (Compl. ¶ 20.)
- "When the ***FDA decides to clear*** a home pregnancy test kit . . ." (Compl. 21.)
- "The [FDA's] Clearance Letter ***directs*** that 'Weeks Estimator' Results should not be expressed as 'weeks pregnant' and should only be explained as the number of weeks that may have passed since ovulation." (Compl. ¶ 22.)
- "The [FDA's] Clearance Letter also instructs that '[p]erformance of the Weeks Estimator should not be displayed on [the] box labeling . . . " (*Id.*)
- "The Clearance Letter also ***requires*** that the Product's 'indications for us' statement 'must be prominently displayed in all labeling, including puch box, and carton labels . . . " (Compl. ¶ 23.)
- "SPD has completely defied the FDA's instructions . . ." (Compl. ¶ 24.)
- SPD "in ***direct contravention of the FDA's restrictions*** and limitations in the Clearance Letter and in violation of the Lanham Act and related state law –

[4] The emphasis in the following experts from C&D's complaint has been added.

consistently advertised it as being capable of estimating how many weeks a woman has been pregnant." (Compl. ¶ 25.)

- "In ***violation of the FDA's directives*** . . ." (Compl. ¶ 27.)
- "Notably, the ***FDA-mandated*** indications for use statement does not appear at all." (Compl. ¶ 34.)
- "In ***violation of the FDA's instructions*** in the Clearance Letter, it is neither in close proximity to the trade name nor in same font size or in bold font." (Compl. ¶ 38.)
- "Nor do they contain the ***FDA-mandated*** indications of use statement." (Compl. ¶ 40.)
- "[I]n ***clearing the Product, the FDA expressly found*** that it cannot be used to estimate how many weeks a woman has been pregnant. The FDA's finding in this regard is correct: the medical profession dates pregnancy from a woman's last menstrual period, not from ovulation." (Compl. ¶ 42.)

These allegations make clear that C&D's Lanham Act claims are precluded.

First, a determination that the Product labeling and related marketing claims for the Weeks Estimator are prohibited as false under the Lanham Act will undermine the FDA's determination that SPD *could* market the Weeks Estimator *using these claims*, or those that "comport substantively" with the claims "approved as accurate by the FDA." *Cytyc*, 12 F. Supp. 2d at 302. Second, *even if* SPD had "defied" the FDA's restrictions and requirements in marketing the Weeks Estimator, as C&D also alleges, enforcement of the FDA's decisions and regulations rests exclusively with the FDA, not C&D or this Court in a private Lanham Act action. Finally, if C&D's allegations concerning the state of the medical science – *i.e.*, that a woman's last menstrual period, not ovulation, is the only appropriate method for determining gestational age, "there is no apparent reason why [C&D] cannot ask the FDA" to take action. *American Home*, 672 F. Supp. at 145. If the FDA agrees, and concludes that "more should be done to prevent deception, or that [SPD] misleads consumers, it can act." *Pom Wonderful*, 679 F.3d at 1177. Indeed, FDA took steps with respect to the very advertising C&D is challenging (perhaps, for all we know, at the prompting of C&D) but required none of the remedies C&D

seeks in its complaint – even though it has the power to impose them. (RJN, ¶ 9, Exh. I.); 21 U.S.C §§332-334; 21 C.F.R. § 810.10 *et seq.* This Court simply cannot adjudicate C&D's claims without treading in exclusive FDA territory.

III. C&D's Lanham Act Claims Are Barred Under The Doctrine Of Primary Jurisdiction.

A related body of law, establishing the "primary jurisdiction" doctrine, calls for "judicial abstention in cases where protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *U. S. v. Philadelphia Nat'l Bank*, 374 U.S. 321, 353 (1963). It "is used to fix forum priority when the courts and an administrative agency have concurrent jurisdiction over an issue." *Mrs. W. v. Tirozzi*, 832 F.2d 748, 758-759 (2d Cir. 1987) (citing *Far E. Conf. v. United States*, 342 U.S. 570, 574-75 (1952)). The aim of the primary jurisdiction doctrine is to "promot[e] proper relationships between the courts and administrative agencies charged with particular regulatory duties" and "to allocate initial decisionmaking responsibility between courts and agencies" so as "to ensure that they do not work at cross-purposes." *Ellis v. Tribune TV Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (citations and quotations omitted). Importantly, it enables the resolution of technical questions of fact through the specialized expertise of the relevant agency *before* judicial adjudication of legal claims. *See U.S. v. Western Pac. RR Co.*, 352 U.S. 59, 64 (1956).

Thus, the doctrine properly applies where – as here – "enforcement of the claim requires resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *U.S. v. Western Pac. RR Co.*, 352 U.S. at 64.

Courts applying the primary jurisdiction doctrine regularly defer to the FDA. *See, e.g., Israel v. Baxter Lab., Inc.*, 466 F.2d 272, 281 (D.C. Cir. 1972) (deferring where "enforcement of claims involves. . . a function clearly within the 'specific competence' of the FDA"); *Healthpoint*

Ltd. v. Stratus Pharm., Inc., 2001 U.S. Dist. LEXIS 22229, *26 (E.D. Tex. June 1, 2001) (finding claims of false and misleading advertising of drug "too close to the exclusive enforcement domain of the FDA"); *Heller v. Coca-Cola Co.*, 646 N.Y.S.2d 524 (N.Y. App. Div. 1996) (same, involving challenge to product labeling), *Bernhardt v. Pfizer, Inc.*, 2000 U.S. Dist. LEXIS 16963, at *6-8 (S.D.N.Y. Nov. 16, 2000) (same re: failure to disclose negative clinical results); *Mut. Pharm. Co. v. Watson Pharm. Co.*, 2009 WL 340117, at *5 (C.D. Cal. 2009) (finding disputes regarding product labels and inserts fall "squarely within the primary jurisdiction of the FDA").

While "[n]o fixed formula has been established" with respect to the doctrine's application, *Nat'l Communs. Ass'n v. AT&T*, 46 F.3d 220, 223 (2d Cir. 1995), the doctrine "potentially applies when federal courts have original jurisdiction to hear the claim and the claim requires the resolution of issues placed within the special competence of an administrative body." *Mrs. W.*, 832 F.2d at 758 (citing *United States v. Western Pac. Ry. Co.*, 352 U.S. at 63-64). Courts generally consider the following four factors when determining whether the doctrine applies:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;
>
> (2) whether the question at issue is particularly within the agency's discretion;
>
> (3) whether there exists a substantial danger of inconsistent rulings; and
>
> (4) whether a prior application to the agency has been made.

Schiller v. Tower Semiconductor, Ltd., 449 F.3d 286, 295 (2d Cir. 2006).

The basis for C&D's claim here are the allegations that (a) the Weeks Estimator does not estimate how long a woman has been pregnant because ovulation is not a legitimate reference point for such an estimate; and (b) the FDA prohibited SPD from communicating any message

inconsistent with C&D's view of the science. Both propositions are clearly matters for FDA decision-making – the first is a question of science and medicine, not of law, and the second is an issue the FDA is uniquely suited to resolve for obvious reasons. In other words, C&D's claim invokes the expertise of those at the FDA in the OIVD in the Center for Devices and Radiological Health ("CDRH"), who are charged with review of medical devices, and in particular, over-the-counter pregnancy tests. Under the SE With Limitations process, OIVD/CDRH has both the right and the responsibility to review and approve advertising language for the Weeks Estimator product. 21 U.S.C. §360c(i)(1)(E). It has done so. (Clearance Letter, p.1.) There is, then, a risk of the court issuing an order at odds with the FDA's determination of language that renders the Product "safe and effective."

C&D recently invoked this doctrine to secure the dismissal of a false advertising claim directed to the FDA-regulated label of one of its Trojan brand condom products. In *Gordon v. Church & Dwight Co.*, 2010 U.S. Dist. LEXIS 32777, 4 (N.D. Cal. Apr. 2, 2010) C&D correctly and successfully argued that a claim like the one it advances now must be dismissed. The principles C&D vindicated there apply with greater force here.

If C&D takes issue with FDA's decisions, C&D has recourse with the FDA: it may file a citizen's petition seeking further the FDA action. 21 C.F.R. §§10.25(a) ("An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action"); *Quick v. Thompkins*, 425 F.2d 260, 261 (5th Cir. 1970) (Recourse must first be sought through administrative channels where allegations are mattes of internal prison administration); *Frank v. Delta Airlines Inc.*, 314 F.3d 195, 201 (5th Cir. 2002) (alleged victims of improper drug testing by airline must first avail themselves of recourse through an administrative procedure under the FAA before seeking review in federal court). Under the SE With Limitations process, the advertising language C&D

challenges is squarely within the purview of the FDA, and should stay there.

IV. C&D's State Law Cause Of Action Is Based On The Same Factual Allegations, And Suffers From The Same Deficiencies, As Its Lanham Act Claim.

C&D bases its cause of action under Section 349 of the New York General Business Law upon the same factual allegations as its Lanham Act claim – that SPD's marketing of the Weeks Estimator constitutes false or misleading advertising. (Compl. ¶¶ 71-75.) Section 349 of the New York General Business Law provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful." N.Y. Gen. Bus. Law § 349. The pleading standard for a Section 349 claim is "substantially the same" as that for pleading a Lanham Act cause of action. *Gottlieb Dev. LLC v. Paramount Pictures Corp.*, 590 F. Supp. 2d 625, 636 (S.D.N.Y. 2008).

For the same reasons that C&D is barred from making its Lanham Act claim – because doing so seeks enforcement of the FDCA and intrudes into the exclusive domain of the FDA to regulate the labeling and marketing of medical devices such as the Weeks Estimator – C&D's state-law false advertising claim must also be dismissed. *Avon Products, Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768, 800 (S.D.N.Y. 1997) (denying false advertising claim under Section 349 "for the same reasons" as denying false advertising claim under the Lanham Act, noting that the standards under the Lanham Act are "substantially the same" as those applied to Section 349 of the New York General Business Law).

V. If The Court Dismisses C&D's Lanham Act Claim, It Should Decline To Exercise Supplemental Jurisdiction Over C&D's State Law And Breach of Contract Claims.

Where all federal-law claims are eliminated before trial, a district court should decline to exercise supplemental jurisdiction over the remaining state-law claims. 28 U.S.C. § 1367; *Carnegie-Mellon Univ. v. Cohill*, 484 U.S. 343, 350 (1988).

If the Court dismisses C&D's Lanham Act claim – as it should, for the reasons stated

herein – the Court should decline to exercise supplemental jurisdiction over C&D's remaining state law claims. Doing so, given that this Action remains in its incipiency, will promote judicial economy, convenience, fairness, and comity. *Kolari v. New York-Presbyterian Hosp.*, 455 F.3d 118, 122 (2d Cir. 2006).

CONCLUSION

For the foregoing reasons, C&D's false advertising claims under the Lanham Act and Section 349 of the New York General Business Law should be dismissed *with prejudice*. [redacted]

[redacted]

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Respectfully submitted,

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